

5002. Powdr-X. (F. D. C. No. 38953. S. No. 26-434 M.)

9 **QUANTITY:** 100 cases, 12 6-oz. pkgs. each, at Minneapolis, Minn., in possession of L. M. Gray, t/a Powdr-X Co.

SHIPPED: During 1946, from Westcliffe, Colo.

LABEL IN PART: (Pkg.) "Powdr-X For Internal Use * * *An impalpable mineral powder consisting of complex silicates of sodium, potassium, calcium, magnesium, aluminum, iron, manganese, zinc, cobalt, nickel, vanadium and titanium, having approximately the following composition: SiO₂ 70.00% MnO .39% Al₂O₃ 12.54% ZnO .076% Fe₂O₃ 2.39% CoO Trace CaO .87% NiO Trace MgO .78% TiO₂ Trace K₂O 4.99% V₂O₅ Trace Na₂O 2.73% Powdr-X Company 5025 Queen Avenue South Minneapolis 10, Minnesota."

LIBELED: 2-16-56, Dist. Minn.

CHARGE: 502 (a)—the labeling of the article, while held for sale, contained false and misleading representations that the article was an adequate and effective treatment for gastric ulcers and gastric intestinal distress; and 502 (f) (1)—the labeling of the article failed to bear adequate directions for use in the treatment of glaucoma, osteomyelitis, tuberculosis of the bone, gangrene, cancer, and cataracts, for which it was recommended orally by L. M. Gray.

DISPOSITION: 4-12-56. Default—destruction.

5003. Pastilla candy, Albert Christy's Big 3 Compound capsules, Mellanine capsules, and rubber exercisers. (F. D. C. No. 38729. S. Nos. 7-484/5 M, 7-487/8 M, 42-390 M, 42-394 M.)

(2) **QUANTITY:** 15 ½-lb. boxes of *Pastilla candy*, 51 60-capsule boxes of *Albert Christy's Big 3 Compound capsules*, 47 100-capsule boxes of *Mellanine capsules*, and 56 unlabeled *rubber exercisers* at Denver, Colo., in possession of Albert Christy.

SHIPPED: The candy and devices were shipped from Hollywood, Calif., on an unknown date, and *Albert Christy's Big 3 Compound capsules* and *Mellanine capsules* were shipped from Detroit, Mich., on 9-29-55.

RESULTS OF INVESTIGATION: During the course of lectures by Albert Christy, representations were made concerning the efficacy of the above-mentioned articles for the conditions and purposes set forth below.

The device involved was a strip of rubber approximately 22 inches long and 2 inches wide.

LIBELED: 12-12-55, Dist. Colo.

CHARGE: 502. (f) (1)—the labeling of the articles, while held for sale, failed to bear adequate directions for use for the diseases, conditions, and purposes for which they were recommended orally by Albert Christy, namely, (*Pastilla candy*) to prevent piles, constipation, congestion, asthma, hay fever, and sinus trouble; (*Albert Christy's Big 3 Compound capsules*) to treat arthritis and to enable one to live longer; (*Mellanine capsules*) to treat arthritis, muscular atrophy, rheumatism, stiff and swollen joints, high blood pressure, low blood pressure, anemia, leukemia, cataract, glaucoma, hardening of the arteries, gallstones, and kidney stones; and (*rubber exercisers*) to prevent cancer of the breast and to treat varicose veins and bursitis.

DISPOSITION: 2-15-56. Default—destruction.

5004. Electrosonic ultrasonic therapy device. (F. D. C. No. 37309. S. No. 88-898 L.)

ct. **QUANTITY:** 2 devices at Milwaukee, Wis.

SHIPPED: 2-2-54, from Albion, Mich., by Scientific Instrument Co.

LABEL IN PART: (Nameplate) "Ultrasonic The Scientific Instrument Company Albion, Michigan U. S. A. Caution To Be Used By Or On The Prescription Of A Physician Only."

ACCOMPANYING LABELING: 2 booklets entitled "Operating Instructions for Electrosonic Instrument," 16 reprints of an article from the Los Angeles Time entitled "Super-Sound Treatment Aids Arthritics, Hospital Says," 25 reprint of an article from Your Life Magazine of September 1952 entitled "Attacking Disease with Sound Waves," 14 reprints of an article from the May 1952 issue of The British Journal of Physical Medicine entitled "Prolapse of Intervertebra Discs Treated with Ultrasonic Waves," 24 reprints of an article from the February 18, 1952 issue of the New York Times entitled "Diseases Treated By Supersonic Aid," 23 reprints of an article from the June 1951 issue of The British Journal of Physical Medicine entitled "Diseases of the Spine Treated With Ultrasonic Waves," 2 reprints of an article from the May 1952 issue of Postgraduate Medicine entitled "The Myofascial Genesis of Pain," 2 leaflets entitled "Latest Reports and Lectures of Scientific Papers on Ultrasonic Therapy," and 3 leaflets entitled "Investigate the New Electrosonic Sound Wave Instrument."

RESULTS OF INVESTIGATION: According to its label and accompanying labeling the device was intended for the production of ultrasonic energy for therapeutic use, but the operator was nowhere provided with information as to the frequency of the ultrasonic energy output and information as to the amount of ultrasonic energy given off by the device for the various settings of the output control mechanism. Since it was essential that the operator of the device be informed as to the frequency of the ultrasonic energy and the amount of ultrasonic energy output for the various settings of the output control mechanism, the labeling of the article did not bear information as to the use of the device as required by regulations.

LIBELED: 10-18-54, E. Dist. Wis.

CHARGE: 502 (f) (1)—the labeling of the article, when shipped, failed to bear adequate directions for use, and the article was not entitled to any exemption from that requirement.

DISPOSITION: 12-1-55; amended 12-20-55. Default—delivered to Food and Drug Administration.

5005. Hemovitameter device. (F. D. C. No. 39023. S. No. 51-480 M.)

QUANTITY: 1 *Hemovitameter device* bearing a segmented dial on which the segments were labeled with such designations as "digestion, blood, tissue, cell life," etc., at Albuquerque, N. Mex., in possession of Dr. S. C. Wyatt, D. C.

SHIPPED: During 1954, from Eckley, Colo., by Hemovitameter Laboratories, Inc.

ACCOMPANYING LABELING: Leaflet reading, in part, "To: Hemovitameter Co. Denver, Colo. * * * Vitality Element 66-4-8 general poison 59-2-7 inflammation 67-2-6 tissue degeneration."

RESULTS OF INVESTIGATION: The consignee placed in local newspapers advertisements by which the device was offered for use in obtaining information concerning various conditions which a person might have.

In actual use the consignee would have the patient take hold of two bars or electrodes that emerged from the device, and "readings" were taken which,